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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/202,681	12/23/1999	ERIC J. MATHUR	09010/044001	3238

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MORRISON & FOERSTER LLP
3811 VALLEY CENTRE DRIVE
SUITE 500
SAN DIEGO, CA 92130-2332

EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/202,681

Applicant(s)

MATHUR ET AL.

Examiner

Richard G. Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8-11, 18, 19, 37-40 and 48-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2 is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 8-11, 18, 19, 37-40 and 48-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicants cancellation of claims 5-7, 13-17, 20, 21, 31-36 and 41-47 and the amendment of claims 2, 8-11, 18, 19, 38, 39 and 50, and the addition of new claims 53-56 in the paper of 6/14/2005, is acknowledged. Claims 1-4, 8-11, 18, 19, 37-40 and 48-56 are present for examination.

Applicants' arguments filed on 6/14/2005 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 4, 8-10, 11, 18, 19, 37-40 and 48-55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (claims 3, 4, 8-10, 37-40 and 48-55 dependent on) is indefinite in that it recites "a polynucleotide which is complementary to the polynucleotide of (a)". It is unclear if it is applicants intent to refer to those polynucleotides that are complementary to the "full length" of the polynucleotide of (a), or whether it is applicants intent that they intend to encompass those polynucleotides are complementary to a smaller portion than full-length of the polynucleotide of (a). The claim is interpreted for examination

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purposes as referring to those polynucleotides which are complementary to the full length of the polynucleotide of (a) and it is suggested that applicants amend the claim to reflect this.

Claims 10 (claim 55 dependent from) and 11 (claims 18 and 56 dependent from) are further rejected under this statute because claims 10 and 11 are drawn to the same polypeptide. Claim 10 is drawn to a polypeptide having phosphatase activity comprising an amino acid sequence encoded by the polynucleotide as set forth in claim 1 or claim 2. It is noted that claim 1 is drawn to a polynucleotide encoding a phosphatase comprising an amino acid sequence as set forth in SEQ ID NO: 28 and this recitation is interpreted as encompassing enzymatically active fragments having phosphatase activity. Thus claim 10 which depends from claim 1 or claim 2 is identical to claim 11.

Claim 19 is indefinite in that it is unclear as to what enzymatically active fragment thereof (referring to SEQ ID NO: 28), applicants are referring. The claim is interpreted as referring to the enzymatic activity of phosphatase activity and it is suggested that applicants amend to reflect such.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 55 and 56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Newly added claims 55 and 56 drawn to host cells comprising the polypeptide of claims 10 and 11 are rejected under this statute because the newly claimed host cells comprising the referred to polypeptides are not supported by the specification at the time of filing and thus considered new matter. Specifically, claims to a genus of "host cells comprising a polypeptide" is considered new matter.

Applicants comments regarding support for such subject matter are acknowledged, however, not found persuasive.

Claims 19 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 19 is directed to all possible polypeptides having a sequence as set forth in SEQ ID NO: 28 or an enzymatically active fragment thereof comprising at least 30 amino acids in length. The specification, however, the single representative species isolated of SEQ ID NO: 28 encompassed by this claim. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these

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polypeptides by any identifying structural characteristics or properties other than the minor structural limitation of "having a sequence as set forth in SEQ ID NO: 28" for which no function is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide comprising the amino acid sequence of SEQ ID NO: 28, does not reasonably provide enablement for any polypeptide "having a sequence as set forth in SEQ ID NO: 28". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. It is noted that a polypeptide "having a sequence as set forth in SEQ ID NO: 28" is interpreted as a polypeptide having any subsequence of SEQ ID NO: 28.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 19 is so broad as to encompass any polypeptide "having a sequence as set forth in SEQ ID NO: 28. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides broadly encompassed by the claims. The claims rejected under this section of U.S.C. 112, first paragraph, place minor if any structural limits on the claimed polypeptides. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to that phosphatase having the amino acid sequence of SEQ ID NO: 28.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the

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instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any polypeptide having the amino acid sequence of SEQ ID NO: 28, because the specification does not establish: (A) regions of the protein structure which may be modified without effecting phosphatase activity; (B) the general tolerance of phosphatases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue of a phosphatase with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain the desired activity and the fact that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable (e.g., see Ngo et al. in *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892), it would require undue experimentation for one skilled in the art to arrive at the majority of those polypeptides of the claimed genus.

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Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of amino acid modifications of SEQ ID NO: 28. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir., 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 19 is rejected under 35 U.S.C. 102(e) as being anticipated by Millan et al. (U.S. Patent No: 5,773,226).

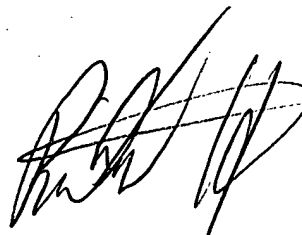
Millan et al. teach a purified polypeptide having a sequence of SEQ ID NO: 10. This purified polypeptide "has a sequence as set forth in SEQ ID NO: 28", as much a polypeptide having a sequence as set forth in SEQ ID NO: 28 is interpreted as encompassing any polypeptide having any sub-sequence such as "Leu-Leu", found within SEQ ID NO: 28. Thus the polypeptide taught by Millan et al. anticipates the polypeptide claimed in claim 19.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'R. G. Hutson', with a stylized flourish at the end.

Richard G Hutson, Ph.D.
Primary Examiner
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rg
8/16/2005